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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|--------------------------|------------------------|
| 10/574,816 | 04/06/2006 | Rui Yuge | 20060477A | 3663 |
| 513 7590 06/27/2007 WENDEROTH, LIND & PONACK, L.L.P. 2033 K STREET N. W. SUITE 800 WASHINGTON, DC 20006-1021 | | | EXAMINER KIM, TAEYOON | |
| | | | ART UNIT 1651 | PAPER NUMBER |
| | | | MAIL DATE 06/27/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|-------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 10/574,816 | Applicant(s) YUGE ET AL. | |
| | Examiner Taeyoon Kim | Art Unit 1651 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above claim(s) 5, 19 and 29-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6 is/are rejected.
- 7) ☒ Claim(s) 7-18 and 20-28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>4/6/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-44 are pending.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-4, 6-18 and 20-28) in the reply filed on Apr. 16, 2007 is acknowledged.

Claims 5, 19 and 29-44 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1-4, 6-18 and 20-28 have been considered on the merits.

Information Disclosure Statement

The information disclosure statement filed Apr. 6, 2006 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no English translation of the foreign reference (EP 0489332A1). It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Claim 15 discloses a limitation to "a rupturing means for

rupturing the bag-type vessel..." There is no support in the specification for the limitation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 4, 17, 18, 24, 25, 27 and 28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 4, 17, 18, 27 and 28 disclose the phrase "one of 1 mL/24 hr atm or more and 10 mL/24 hr atm or more." It is not clear what subject matter the phrase intends to point out. It can be interpreted as one value of gas permeability from 1 mL/24 hr atm or more, in addition to 10 mL/24 hr atm or more, or as either 1 mL/24hr atm or more or 10 mL/24hr atm or more. Clarification is required.

Claims 24 and 25 disclose the phrase "in proximity to". It is vague what subject matter the phrase intends to claim. There is no description or guideline to define the "proximity" in the specification as well as claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by OriGen PermaLife Bag (<http://web.archive.org/web/20010307123107/http://www.origen.com/PermaLife.html>) or JP 06-013499 (IDS reference).

Claims 1-4 and 6 are drawn to a cell handling device having a liquid-tight vessel comprising cells and medium, a mouth connecting interior and exterior of the vessel, and a part of the vessel being gas permeable (claim 1); a limitation to the vessel being gas-permeable in whole vessel (claim 2); a limitation to the device having oxygen permeability more than 1 mL/24 hr atm or more than 10 mL/24 hr atm (claim 3); a limitation to the device wherein the gas permeable region being composed of a porous film (claim 4); a limitation to the device further comprising a volume varying means (claim 6).

The article entitled "OriGen PermaLife Bag" teaches a cell culture bag (a vessel) having a mouth (opening) for transfer the handling medium (culture medium) between an interior and an exterior of the bag, and the bag is made of Teflon film (porous film) (see whole document). Although it does not particularly teach a volume varying means, since the bag is flexible and squeezable, the bag has an inherent property to vary the volume the medium by squeezing or by simply inverting the bag upside down. Furthermore, the bag has oxygen permeability more than 10 mL/day (see the table in p.2).

The IDS reference of JP 06-013499 discloses a flexible cell culture container having oxygen permeability at 600-3000 ml/m² 24 hr at atm and made of resin (gas

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permeable resin) (see paragraph [0006]). It has a mouth (opening) and foldable to change the volume of the container (see Fig. 2; paragraph [0015-0017]). Although it is not clear the surface area of the cell culture container to calculate total oxygen permeability of the bag, it is at least more than 1 mL/24 hr atm because the permeability given for the unit area (cm²) of the container would be 0.06-0.3 mL/24 hr and if the bag has capacity of holding more than 100 ml of medium (see paragraph [0017]), the surface area of the containing would be more than 100 cm², considering the dimension given in the OriGen PermaLife Bag article for 120 ml capacity. Then the permeability of oxygen of the containing in the reference would be more than 30 mL/24 hr. atm.

Thus, the reference anticipates the claimed subject matter.

Allowable Subject Matter

Claims 7-18 and 20-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

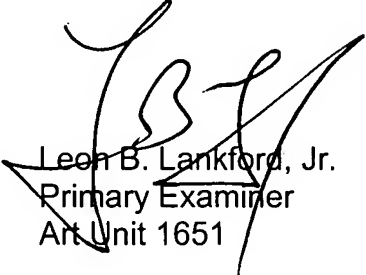
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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